



NTP
National Toxicology Program

NTP Testing Program: Proposed Research Projects

Dr. Scott Masten

NTP Board of Scientific Counselors Meeting

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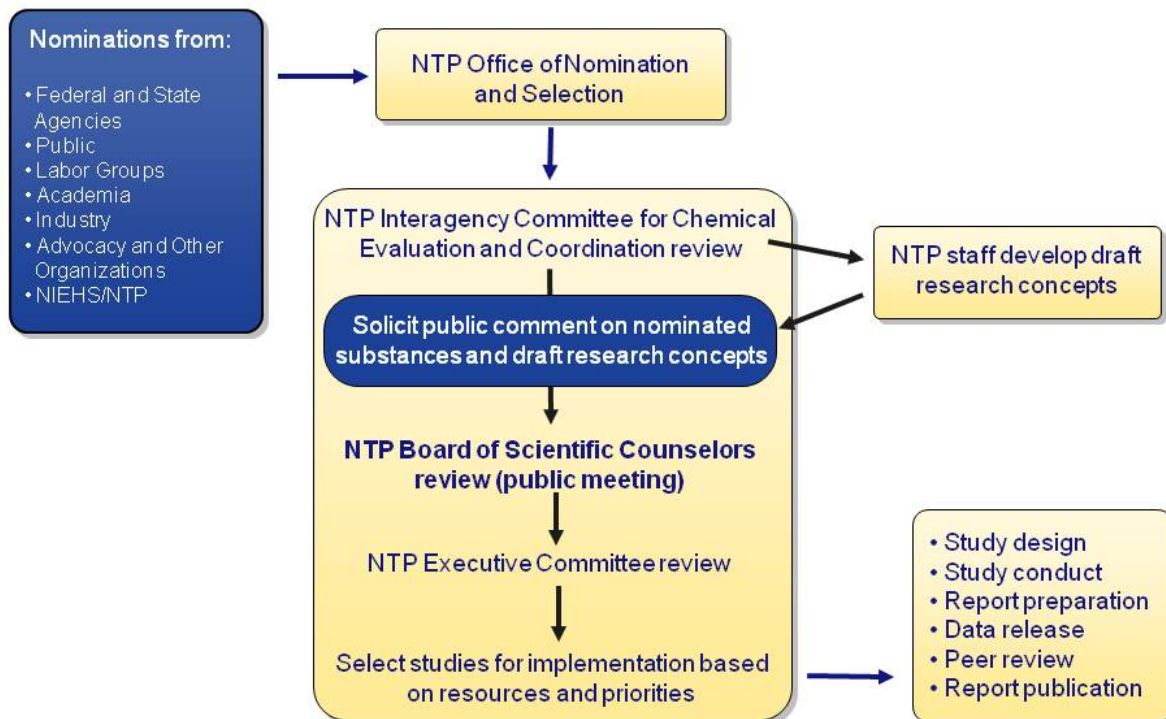


Development of NTP Research Projects

- Toxicological research programs are developed by NTP staff internally and in response to external nominations
- Multiple levels of review to determine merit and priority for study
- Selection for study primarily on the basis of:
 - Known or anticipated human exposure
 - Production levels
 - Suspicion of toxicity based on chemical structure or existing health effects data
 - Availability of adequate toxicological data
 - Extent of public concern
 - Utility of additional studies for public health decision-making
- Iterative, tiered approach to study design and conduct



NTP Study Nomination Review Process





New Research Projects for BSC Review

- NTP staff have prepared draft research concepts for 5 new nominations
 - Proposed approach to address toxicological data needs for each substance or issue, not experimental study design
 - Outline data gaps, key issues, hypotheses and/or specific aims
- Proposed research projects
 - Dimethylamine borane (Dr. Dori Germolec)
 - Ethylene glycol 2-ethylhexyl ether (Dr. Chad Blystone)
 - Bisphenol AF (Dr. Matt Stout)
 - L- β -Methylaminoalanine (Dr. Mike Sanders)
 - Triclosan (Dr. Paul Howard)
- New nomination with no studies recommended
 - Hydroxyurea (Dr. Scott Masten)



BSC Review of Proposed Research Projects

Charge: To determine whether sufficient justification is provided for the use of NTP testing program resources to carry out proposed research projects as outlined in the draft research concept documents.

Action: The NTP BSC will review and comment on draft NTP research concepts with respect to the specific charge questions. A research concept is a brief document outlining the nomination or study rationale, and the significance, study approach, and expected outcome of a proposed research program.



Charge Questions for BSC Review of Proposed Research Projects

- Please comment on the clarity and validity of the rationale for the proposed research program as articulated in the NTP research concept document.
- Please comment on the merit of the proposed research program relative to the goals of the NTP. *The NTP's purpose is to: Provide information on potentially hazardous substances; Develop and validate improved test methods; Strengthen the science base in toxicology; Coordinate toxicology testing programs across DHHS.*
- Please comment on the scope of the proposed program and its appropriateness, relative to the public health importance of the issue or substance being proposed for study. Are there additional studies that should be considered as part of this research program? Should some of the proposed studies be considered lower priority?
- What priority (low, moderate, or high) should NTP give to the proposed research program given the rationale, merit and scope?



Today's Session

- Introduction to testing program project reviews
- Presentation of research concepts by NTP project leaders
- Public comments
- Comments from Board and *ad hoc* reviewers
 - Response to charge
- Board discussion



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Questions and Comments